UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/402,450	09/01/89	MURAKAWA G	

EXAMINER
ESCALLON, M

EDWARD S. IRONS
919 - 18TH STREET, N. W., STE. 800
WASHINGTON, DC 20006

ART UNIT	PAPER NUMBER
1814	13

DATE MAILED: 03/19/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 12-5-91 ☑ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 33 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-17 & 26-30 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 18-25 & 31-33 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 1-17 and 26-30 have been canceled. Claims 18-25 and newly presented 31-33 are still at issue and are present for examination.

Applicants' arguments filed on December 4, 1991, paper No 10, have been fully considered and they are deemed to be persuasive to overcome most of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification as originally filed, does not provide support for the invention as now is being claimed.

The manner in which false positive or false negative data is "discerned" by the claim 18 process has not being enabled by the specification as originally filed. Applicants are directed to

page 8, of the specification where by their own admission state that "the process of the invention is useful to amplify and detect viral RNA from any source" and not to "discern" false positive or negative data. Applicants' examples are directed to how RNA sequences isolated from HIV infected cells are efficiently utilized for amplification and detection by southern hybridization.

Claims 18-25 and 31-33 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 18 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "discerning" use by applicants in the preamble of claim 18 is improper. The term is directed to a mental step which is not statutory subject matter and therefore is given no patentable weight. Suggested language would be "detecting" or "identifying". Also, steps iv and v are confusing. Applicants' steps are directed to the hybridization of the amplification products with probes homologous to the target and the reference sequences. Furthermore, applicants refer to the hybridization with another of "said probes". It is not clear what "probes" applicants are referring to in the removal of the probes or if applicants are using the same probes in both steps. It is not

clear how the use of a third set of probes would affect the step (v) since the determination is done by the hybridization with the first set of probes that are homologous to the target and reference sequences. Finally, it is not clear if a single probe homologous to both the target and reference sequence is intended or if multiple pobes are intened.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 18-23 and 31-33 are again rejected under 35 U.S.C. § 103 as being unpatentable over Mullis et al. in view of Ratner et al.

This rejection is essentially identical to that set forth in the last Office Action and will not be repeated. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Applicants argues that Mullis et al. do not

disclose "reference sequence" contrary to applicants' assertion Mullis et al. disclose the amplification of viral RNA in the bridging sentences between columns 7 and 8. It is disclosed the alternative adding of either one or two primers so as to facilitate the amplification second strand target sequence, followed by amplification of both strands by two primers, in column 9, lines 5-49. The whole process is summarized by Mullis et al. in column 2, line 63 through column 3, line 33, wherein the detection step with a labeled probe is cited in column 3, lines 25-27. Mullis et al. is a general but very detailed teaching as to the PCR method. Ratner et al. give the complete HIV genomic sequence as well as discussion of regions contained therein which clearly therefore gives the required knowledge for not only many possible primer sequences but probes as well.

Therfore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the PCR technique of Mullis et al. to HIV amplification and detection because Mullis et al. supply the general technique with a great deal of guidance as to its application and Ratner et al. supplies the sequence information which is the last required data for the use of PCR in HIV amplification and detection.

Claim 24 and 25 are again rejected under 35 U.S.C. § 103 as being unpatentable over Mullis et al in view of Ratner et al. as applied to claim 18-23 and 31-33 above, and further in view of Hennighausen et al. and Wathen et al.

This rejection is essentially identical to that set forth in the last Office Action and will not be repeated. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Hennighausen et al. give the complete HCMV immediate early (IE1) genomic sequence. Wathen et al. give probes that hybridize late HCMV genes. Therefore as applied above, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to apply the PCR technique of Mullis et al. to HMCV amplification and detection because Mullis et al. supply the technique with a great deal of guidance and Hennighausen et al. and Waten et al. supply the sequence information which is the last required data for the use of PCR in HCMV (IE) or late regions for amplification and detection.

Claims 18-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-53 of copending application Serial No. 07/180,740. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to detect an RNA virus via PCR methodology with primers and probes of conserved transcript sequences that are known in the prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is

primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Miguel H. Escallon, Ph.D. whose telephone number is (703) 308-0376.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M.H.E.
March 18, 1992

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180